IN THE UNITED STATES OF AMERICA NORTHERN DISTRICT OF TEXAS LUBBOCK DIVISION

State of Texas,

Plaintiff,

v.

United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services,

Defendants,

and

City of Columbus, Ohio; City of Madison, Wisconsin; and Doctors for America,

Proposed Intervenor-Defendants. Civil Action No. 5:24-cv-00204-H

MEMORANDUM OF LAW OF PROPOSED INTERVENOR-DEFENDANTS IN OPPOSITION TO PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

The confidentiality of patient health information is a cornerstone of effective health care. For 25 years, patient privacy protections have been governed by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (Pub. L. 104–191, 110 Stat. 1936). HIPAA and its implementing regulations (the "Privacy Rules") ensure that identifiable patient information is used and disclosed appropriately. Patients and clinicians alike rely on the protections afforded by the statute to use and disclose patient information efficiently, effectively, and confidentially. At the beginning of this lawsuit, Plaintiff challenged both the Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (the "2000 Privacy Rule" or the "2000 Rule") and the HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32976 (Apr. 26, 2024) (codified at 45 C.F.R. pts. 160, 164) (the "2024 Rule" or the "Rule"). Both challenges fail.

As a threshold matter, Plaintiff has now abandoned its challenge to the 2000 Privacy Rule, the nearly 25-year-old rule that has provided the foundation for implementation of HIPAA nationwide. Its claims concerning the 2000 Rule are indisputably time-barred and would also fail on the merits. Plaintiff apparently has recognized the futility of its claim—it has not moved for summary judgment as to the 2000 Rule, nor has it offered any opposition to Defendants' motion on this issue. Plaintiff therefore has abandoned its claims as to the 2000 Rule and judgment as to that Rule should be entered in Defendants' favor.

Instead, in its motion for partial summary judgment, Plaintiff challenges only the 2024 Rule, but that challenge also fails. The 2024 Rule is consistent with the statutory authority expressly delegated to the Department of Health and Human Services (the "Department" or "HHS") by Congress in HIPAA and is not arbitrary or capricious.

Congress directed the Department to "promulgate final regulations" containing "standards with respect to the privacy of individually identifiable health information." Appx. 561 (42 U.S.C. § 1320d-2 note (codifying Pub. L. 104–191, title II, § 264)). This explicitly includes the "rights that an individual who is a subject of individually identifiable health information should have"; "[t]he procedures that should be established for the exercise of such rights"; and "[t]he uses and disclosures of such information that should be authorized or required." *Id.* Congress further directed the Department to "adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1).

The 2024 Rule is entirely consistent with these statutory guidelines as a matter of law. In arguing that the 2024 Rule unlawfully limits its investigative authority, Plaintiff ignores HIPAA's express preemption of contrary state law and fails to demonstrate that the Rule implicates any of the limited exceptions enumerated in the statute. The 2024 Rule does not impede legitimate law enforcement activity, as it provides exceptions for when law enforcement officials have a legitimate basis to obtain confidential information and follow the required steps to do so. This is not just the Department's interpretation of HIPAA—it is clear from the statute's text.

In promulgating the 2024 Rule, the Department considered the relevant facts and acted well within its discretion. As authorized under HIPAA, the Department struck a balance between protecting patient records regarding particularly sensitive medical care without unduly infringing on state authority preserved by the statute. Plaintiff's argument that the 2024 Rule is arbitrary and capricious is little more than an attempt to substitute its judgment—and Texas's policy objective—for the Department's reasoned judgment. That is insufficient to prevail on an Administrative Procedures Act ("APA") claim.

Finally, even if the Court finds in favor of the Plaintiff, the relief granted should be narrow.

Patients and clinicians alike rely on the protections afforded by the Privacy Rules to use and disclose information regarding patient health care efficiently, effectively, and confidentially. The Privacy Rules are essential to the provision of health care and protection of the clinician-patient relationship throughout the United States. Universally vacating, enjoining, and setting aside the 2024 Rule (much less the 2000 Rule) would have devastating consequences for patients, providers, cities, and all that participate in the health care system.

For the reasons stated below and in the briefs of the Department and individual Defendants (collectively, "Defendants"), this Court should grant Defendants' motion for summary judgment, deny Plaintiff's cross-motion for partial summary judgment, and enter judgment for the Defendants.

BACKGROUND

The background regarding HIPAA and the Privacy Rules is set forth in greater detail in briefings in support of Defendants' motion for summary judgment. *See* Defs.' Mem. in Supp. of Mot. to Dismiss or the in the Alternative for Summ. J. ("Defs.' Mem.") at 3–9, ECF No. 20; *see also* Proposed Intervenor-Defs.'s Mem. in Supp. of Mot. to Dismiss or in the Alternative for Summ. J. ("Proposed Intervenors' Mem.") at 4–6, ECF No. 26-3.

In 1996, Congress enacted HIPAA to "improve . . . the efficiency and effectiveness" of health care, in part by "establish[ing] . . . standards and requirements for the electronic transmission of certain health information." Appx. 549 (42 U.S.C. § 1320d note (codifying Pub. L. 104–191, title II, § 261)). Congress directed HHS to submit "detailed recommendations on," and ultimately promulgate rules containing, "standards with respect to the privacy of individually identifiable health information." Appx. 561 (42 U.S.C. § 1320d-2 note).

Congress also included an express preemption provision in HIPAA, mandating that "a provision or requirement under [HIPAA], or a standard or implementation specification adopted

or established under [HIPAA], shall supersede any contrary provision of State law," with limited exceptions, including for "public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(a)(1), (b). Congress made clear that the privacy regulations to be promulgated by HHS would constitute a floor nationwide, preempting and superseding less stringent protections but not contrary provisions of state law that may be "more stringent" than the requirements of HHS's HIPAA rules. Appx. 561–62 (42 U.S.C. § 1320d-2 note). This floor grounds patient privacy expectations nationwide and provides health care providers and industry professionals alike with a standard starting point for their patient data privacy programs.

In 2000, the Department proposed and ultimately promulgated the 2000 Privacy Rule, which established a set of national standards for protecting certain health information. *See* Appx. 004 (65 Fed. Reg. at 82462 (Dec. 28, 2000)). HIPAA expressly contemplated and authorized amendments to the 2000 Privacy Rule to address developments consistent with the principles and policy set forth by Congress. 42 U.S.C. § 1320d-3(b)(1) ("[T]he Secretary shall review the standards adopted . . . and shall adopt modifications to the standards (including additions to the standards), as determined appropriate.").

The 2024 Rule was one such amendment, promulgated to "amend[] provisions of the [2000] Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advance[] the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." Appx. 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). 1

¹ On June 18, 2025, in a decision not binding on this Court, the *Purl* court granted Plaintiffs' motion for summary judgment with respect to the 2024 Rule. *Purl v. U.S. Dep't of Health and Hum. Servs.*, No. 2:24-CV-228-Z, 2025 WL 1708137, at *1 (N.D. Tex. June 18, 2025). Respectfully, that decision was flawed in several respects, as this brief sets forth. However, Proposed Intervenors also note that the *Purl* decision provides further support for Proposed

ARGUMENT

I. Texas Concedes the Validity of the 2000 Rule, but Any Challenge to That Rule Would Be Time-Barred and Meritless

Plaintiff has abandoned its claim that the 2000 Rule, the decades-old foundation of health information privacy in the United States, is contrary to statute, exceeds the authority granted to the Department by Congress, and is arbitrary and capricious. See Compl., ECF No. 1, at ¶ 65-80, 84; 90-103; see also Br. in Supp. of Pl.'s Resp. in Opp'n to Defs.' Mot. to Dismiss or Mot. for Summ. J., and Pl.'s Mot. for Partial Summ. J. ("Pl.'s Br.") at 25–36, ECF No. 57. When a plaintiff fails to advance a claim or to rebut Defendants' arguments as to the claim on a motion for summary judgment, then the claim is deemed abandoned. Vela v. City of Houston, 276 F.3d 659, 678 (5th Cir. 2001) ("[A] party 'in his opposition to a motion for summary judgment cannot abandon an issue and then . . . by drawing on the pleadings resurrect the abandoned issue."") (quoting Hargrave v. Fibreboard Corp., 710 F.2d 1154, 1164 (5th Cir. 1983)); Black v. N. Panola Sch. Dist., 461 F.3d 584, 588 n.1 (5th Cir. 2006) (Plaintiff's "failure to pursue this claim beyond her complaint constituted abandonment."); Ragas v. Tenn. Gas Pipeline Co., 136 F.3d 455, 458 (5th Cir. 1998) ("Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment." (quotation omitted)). Indeed, courts in this District have deemed claims abandoned under similar circumstances. See, e.g., *Thompson v. Fay Servicing, LLC*, No. 3:18-CV-00362-BT, 2019 WL 6064075, at *2–3 (N.D. Tex.

Intervenors' Motion to Intervene. The *Purl* court states numerous times that the government defendants "waived their merits arguments," and "do not respond to Plaintiffs' arguments." *Id.* at *6, 11.

Further, in the interest of judicial economy, Proposed Intervenors respectfully note that the Court could grant summary judgment to Defendants with respect to the 2000 Rule and stay consideration of the 2024 Rule, as it as has already been vacated, pending further proceedings in the *Purl* case.

Nov. 14, 2019) (citing Arias v. Wells Fargo Bank, N.A., No. 3:18-CV-00418-L, 2019 WL 2770160, at *2 (N.D. Tex. July 2, 2019)); Johnson v. State Farm Lloyds, No. 4:21-CV-158-Y, 2023 WL 2529561, at *3-4 (N.D. Tex. Feb. 7, 2023). Plaintiff's combined cross-motion and opposition make no reference to the 2000 Rule at all—either in support of the Complaint's allegations or to refute Defendant's arguments in support of dismissal or summary judgment as to that Rule. As a result, it has abandoned its claims as to the 2000 Rule.

Even if Plaintiff had not abandoned its challenge to the 2000 Rule, its arguments would be time-barred and meritless. Plaintiff must establish the timeliness of its claims under the APA. *See* 28 U.S.C. § 2401(a); *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 808 (2024). Where, as here, Congress has not specifically enacted another statute of limitations, claims under the APA must be "filed within six years after the right of action first accrues." *Corner Post, Inc.*, 603 U.S. at 808 (quoting 28 U.S.C. § 2401(a)) (emphasis removed). A claim accrues when it is "complete and present," at which point a litigant can sue. *Id.* at 809. The only injury Plaintiff plausibly alleges stemming from the 2000 Rule is a generalized injury arising from the promulgation of the rule itself—not any subsequent injury caused by its continuing enforcement. Compl. ¶ 8. Even under *Corner Post, Inc.*, the APA's six-year limit expired nearly 20 years ago. 603 U.S. at 809.

Plaintiff's challenge to the 2000 Rule is also facially meritless. The Department acted within its delegated statutory authority in promulgating the 2000 Rule and appropriately exercised its discretion, as the APA requires. *See* Proposed Intervenors' Mem. at 9–11; *see also* Defs.' Mem. at 15-20. Plaintiff makes no allegation in the complaint and no argument in their summary judgment briefing that the Department failed to consider any relevant factors. *See*, *e.g.*, Compl. ¶¶ 24–35 (making no allegations regarding the rulemaking process). To the contrary, the

undisputed record of rulemaking establishes that the Department engaged in extensive consultation with federal and state agencies and considered hundreds of public comments—conclusive evidence that the Department's promulgation of the 2000 Privacy Rule was not "arbitrary, capricious, [or] an abuse of discretion." Proposed Intervenors' Mem. at 11–12; 5 U.S.C. § 706(2)(A); see Barr v. Sec. & Exch. Comm'n, 114 F.4th 441, 447 (5th Cir. 2024) ("Agency decisions are presumptively valid; the petitioner bears the burden of showing otherwise." (cleaned up)); Huawei Techs. USA, Inc. v. Fed. Commc'ns Comm'n, 2 F.4th 421, 434 (5th Cir. 2021) ("Our role is to determine whether the agency's decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." (cleaned up)); Associated Builders & Contractors of Tex., Inc. v. Nat'l Lab. Rels. Bd., 826 F.3d 215, 224–25 (5th Cir. 2016) ("To affirm an agency's action, we need only find a rational explanation for how the [agency] reached its decision." (emphasis removed)).

Because Plaintiff has abandoned its claims as to the 2000 Rule, and those claims have always been time-barred and meritless, the Court should grant judgment in favor of Defendants as to the 2000 Rule.

II. The 2024 Rule Is Consistent with HIPAA and Not in Excess of the Department's Authority Under the Statute

Plaintiff's assertion that the 2024 Rule imposes a broad and unauthorized "limit" on states' traditional powers over public health and welfare is misguided and misunderstands the plain text of the HIPAA statute. HIPAA is clear about where and how it limits state actors—it expressly preempts contrary state laws subject only to limited exceptions—and Plaintiff fails to show that any of those exceptions apply here. To the contrary, Plaintiff's analysis largely sidesteps meaningful engagement with the full text of the preemption provision, 42 U.S.C. § 1320d-7, and instead strains to redefine the terms "invalidate or limit" and "public health surveillance, or public

health investigation or intervention." *Id.* Plaintiff's interpretation of the meaning of "public health surveillance, or public health investigation or intervention," *id.*, is not the best reading of the statutory language, given its plain meaning as originally intended by Congress. Moreover, the statutory language comfortably authorizes the 2024 Rule, which falls well within the scope of what Congress intended to delegate to the agency.

A. HIPAA Provides for Broad Preemption of State Laws with Only Narrow and Enumerated Exceptions

In arguing that the 2024 Rule limits its police powers and investigative authority, Plaintiff ignores the critical preemption provision Congress included in the HIPAA statute. It contains a clear and express preemption of contrary state law, 42 U.S.C. § 1320d-7(a), paired with a limited set of exceptions, *id.* §§ 1320d-7(b), (c). Plaintiff fails to address this careful construction entirely and instead asks the Court to set aside Congress' intention to create specific and narrow exceptions to the preemption provision. It asks the Court to credit some nebulous and (in its view) inviolable "State investigative authority," regardless of the statute's express preemption language. Pl.'s Br. at 27. And in so doing, tries to carve out a mile-wide exception that would entirely swallow the default rule of preemption.

Plaintiff does not challenge HIPAA's general preemption provision. Nor could it—all that is required of Congress is a plain statement that makes its intention "clear and manifest" to "preempt the historic powers of the States." *Will v. Mich. Dep't. of State Police*, 491 U.S. 58, 65 (1989) (citation omitted). HIPAA clearly does so. 42 U.S.C. § 1320d-7(a) ("[A] provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall supersede any contrary provision of State law . . ."). Such preemption is necessary to further the core purpose of HIPAA, and the rules promulgated thereunder, to provide uniform, nationwide standards for the secure exchange of private health

information. *Id.* §§ 1320d-2(a)(1), (d); Appx. 549 (42 U.S.C. § 1320d note). This general preemption provision is subject only to limited exceptions:

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

42 U.S.C. § 1320d-7(b).

Plaintiff largely ignores this clear and narrow preemption provision and argues broadly that the Rule is invalid because it limits Plaintiff's "traditional police powers over public health and welfare." Pl.'s Br. at 26. However, "[q]uestions of statutory interpretation begin and end, as they must, with the text itself." *Kelley v. Azar*, No. 4:20-CV-00283-O, 2021 WL 4025804 at *10 (N.D. Tex. Feb. 25, 2021). The list of exceptions contains no general terms, references to state police powers, or any other open-ended language. There are only six specific and identified exceptions to the broad preemption explicitly provided for by the statute. *See* 42 U.S.C. § 1320d-7(b). For the 2024 Rule to run afoul of the HIPAA statute, Plaintiff must demonstrate that at least one of these enumerated carveouts is implicated. Plaintiff fails to make any such showing.

B. The Plain Meaning of the Term "Public Health" Indicates None of HIPAA's Preemption Exceptions Apply

Plaintiff claims that the 2024 Rule is unlawful because it "limits" the disclosure of patient records necessary for "public health investigations," in violation of 42 U.S.C. § 1320d-7. Pl.'s Br. at 28. However, Plaintiff focuses entirely on whether the protections established by the Rule "limit" its authority as the term is used in the statute, *see* Pl.'s Br. at 26 ("whether the 2024 Rule 'exceeds statutory authority turns on the meaning of 'limit' in HIPAA'"), and ignores the threshold question of whether the activity Plaintiff seeks to conduct implicates "public health investigations." It does not.

As an initial matter, Plaintiff acknowledges that the investigations it seeks to conduct are

not "public health investigations," stating that "[t]he purpose of collecting the information is to determine whether unlawful conduct has occurred." Pl.'s Br. at 28. As described below, the plain meaning of "public health investigation" as intended by Congress does not extend to such purposes.

"Public health" is a well-established term of art used to describe *population-level* efforts to study and promote health, such as those carried out by the Intervenor-Defendant cities' public health departments. This is a simple textual analysis. The dictionary definition of public health is: "the art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science." "Public Health," MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed., 2014). Definitions of the term from medical and legal dictionaries, the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry, and many states are in accord: public health information is that which affects the health of communities. Appx. 397 (89 Fed. Reg. at 33001 nn.233–34 (Apr. 26, 2024) (citing "Health, Public Health," BLACK'S LAW DICTIONARY (11th ed. 2019) and "Public Health," STEDMAN'S MEDICAL DICTIONARY 394520)). On the other hand, disclosures of individual health information merely to punish that individual for the care are not public health disclosures.

Plaintiff's assertion that "HHS is not entitled to deference" under *Loper Bright Enterprises* v. Raimondo, 603 U.S. 369 (2024), therefore misses the mark. Pl.'s Br. at 26. Deference is neither needed nor requested. The plain meaning of "public health" is far from novel, and instead is clear based on its use in dictionaries and by medical practitioners, by other government agencies, and in other statutes. The Department's definition of "public health" as referring to "population-level activities to prevent disease in and promote the health of populations" is fully consistent with that plain meaning. 45 C.F.R. § 160.103; Appx. 396–97 (89 Fed. Reg. at 33000–01 (Apr. 26, 2024)).

The 2024 Rule, which concerns individuals' health records and the investigation or imposition of liability on specific individuals for the mere act of seeking or providing legal health care, therefore has no impact on the public health-related exceptions in the HIPAA statute.

Although Plaintiff claims that the 2024 Rule defines public health too narrowly, it fails even to offer a competing definition of the term that incorporates investigation into individualized health care—let alone demonstrate that this is the term's 'plain meaning' through references to dictionaries or common usage. Such an expansive (and unsupported) view of state primacy in the public health sphere, translated into a broad construction of the term "public health" in 42 U.S.C. § 1320d-7(b), would make for an exception that swallows the Rule and violates the balance HIPAA carefully struck between federal and state legislative spheres. As Plaintiff would construe the term, nearly any "authority, power, or procedure" could be characterized as relating to "public health," thereby subverting the HIPAA preemption provision entirely.

Plaintiff further argues that 42 U.S.C. § 1320d-7(b) protects "reporting" so that the state can "investigate and prosecute violations" of law "governing abortions and 'gender-transition' procedures on minors." Pl.'s Br. at 31; see *also id.* at 29 ("This limitation is particularly acute as it applies to abortion."). But § 1320d-7(b)'s public health provision does not protect "reporting"—it refers specifically to "public health surveillance, or public health investigation or intervention." (emphasis added). See also Appx. 400 (89 Fed. Reg. at 33004 (Apr. 26, 2024)) ("A covered entity may continue to use or disclose PHI for all the public health activities and purposes listed in section [1320d-7(b)]"). Plaintiff is reading words into the statute that are not there. *See* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation Of Legal Texts 107 (2012).

C. The 2024 Rule Does Not "Limit" Valid State Public Health Authority Within the Meaning of HIPAA

Even if the 2024 Rule implicates identifiable "public health" activities within the meaning

of the exceptions to HIPAA's preemption provision, it still would not violate HIPAA for two related reasons: Plaintiff misconstrues the meaning of the term "limit" as used in the statute and misconstrues the practical application of the 2024 Rule.

First, Plaintiff adopts a remarkably and insupportably broad definition of the word "limit," as used in the phrase "invalidate or limit" in 42 U.S.C. § 1320d-7. Under Plaintiff's reading, any HHS requirement that even marginally slows a legitimate request—from the use of new reporting software to the presence of a short attestation form—would be an impermissible "limit" on state authority. See Compl., ECF No. 1 at ¶¶ 21, 28, 52; Pl.'s Mem. at 30. Such a reading is only possible because Plaintiff reads the word "limit" in a vacuum and ignores the actual text and context of the word "limit." Contra Sackett v. EPA, 598 U.S. 651, 674 (2023) ("The meaning of a word 'may only become evident when placed in context . . .") (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132, (2000)); SCALIA AND GARNER, READING LAW, 195.

Here, the word "limit" follows the word "invalidate," and, applying the *noscitur a sociis* canon of construction, must be understood with reference to its partner. 42 U.S.C. § 1320d-7(b). Invalidate means that rules promulgated under HIPAA may not *literally* eliminate the "authority, power, or procedures established under any law" outlined in § 1320d-7(b). "Limit," then, is best understood to refer to *substantial impairment* of the same—in other words, HHS may not effectively eliminate one of the enumerated powers, even if it has not been literally invalidated. To find otherwise would allow "the exception to swallow the rule" of preemption. *Matter of Thomas*, 931 F.3d 449, 454 (5th Cir. 2019) (interpreting statute to avoid having the exception swallow the rule); *see also Bloate v. U.S.*, 559 U.S. 196, 210 (2010) (same); *Cuomo v. Clearing House Ass'n, L.L.C.*, 557 U.S. 519, 530 (2009) (same).

Second Plaintiff misconstrues the actual function of the 2024 Rule. The rule is narrow in

scope and effect such that it does not "limit" any preserved state authority, even assuming such authority is implicated. The 2024 Rule sets new standards governing requests for information about *lawful* reproductive health care for the *purposes of investigating or imposing liability* on a person for the *mere act* of seeking or providing the care. 45 C.F.R. § 164.502(a)(5)(iii)(A). It "does not seek to prohibit disclosures of PHI where the request is for reasons *other than* investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating [lawful] reproductive health care." Appx. 390 (89 Fed. Reg. at 32994 (Apr. 26, 2024)) (emphases added). As explained above, the 2024 Rule reaffirms protection of individuals' personal records but explicitly does not cover population-level information—states remain free to seek and collect anonymized data to carry out their public health operations. The Rule only prevents disclosure of individual records regarding lawful health care, when the purpose of the request is to investigate or prosecute an individual on the sole basis of having obtained or provided that lawful care.

Under any reasonable reading of the HIPAA statute—and even under Plaintiff's expansive (but incorrect) reading—the 2024 Rule does not run afoul of any of the enumerated powers reserved to the states in the statute's exceptions to preemption. 42 U.S.C. § 1320d-7(b). The 2024 Rule prevents only disclosure of records regarding lawful health care, when the purpose of the request is to investigate or prosecute an individual on the sole basis of having obtained or provided that lawful care.

D. The 2024 Rule Is Otherwise Consistent with HIPAA's Grant of Authority

To the extent Plaintiff argues that the 2024 Rule otherwise exceeds the authority granted to HHS by Congress, those arguments are equally unavailing.

HHS promulgated the 2024 Rule pursuant to an express grant of authority from Congress. Congress, through HIPAA, directed HHS to promulgate standards with respect to the privacy of

individually identifiable health information and provided detailed guidance in the statute about what these standards should do: improve "the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information." Appx. 549 (42 U.S.C. § 1320d note). To fulfill this directive, Congress directed the HHS Secretary to recommend privacy standards that addressed "[t]he rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required." Appx. 561 (42 U.S.C. § 1320d-2 note). Congress also set itself a deadline. If it failed to act on the Secretary's recommendations and enact legislation within three years, it empowered the Secretary to "promulgate final regulations containing such standards." Id. Congress further "contemplated that [HHS's] rulemaking would not be static," and "specifically built in a mechanism to adapt such regulations as technology and health care evolve." Appx. 377 (89 Fed. Reg. at 32981 (Apr. 26, 2024)). To that end, it directed "the Secretary [to] review the standards adopted . . . and [to] adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1).

That is precisely what HHS did in promulgating the 2024 Rule. As provided by the statute, the Secretary adopted modifications that he determined were appropriate in light of the "changing legal landscape." Appx. 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). The Secretary explained

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The 2024 Rule is merely the latest in a history of lawful updates to the baseline HIPAA privacy rules, adopted in accordance with HIPAA's mandate that HHS "promulgate," "review," and "adopt modifications," to the rules. Appx. 561 (42 U.S.C. § 1320d-2 note); 42 U.S.C. § 1320d-3. As here, modifications to the HIPAA privacy rule have historically been made in accordance with changes to the health law landscape. For example, in 2009, the Breach

in detail that in the aftermath of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), "the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect" had increased, because the threat of disclosure for purposes of conducting an investigation or imposing liability "is likely to chill an individual's willingness to seek lawful health care treatment or to provide full information to their health care providers " Appx. 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). This, in turn, threatens the "efficiency and effectiveness of the health care system," Appx 549 (42 U.S.C. § 1320d note), that HIPAA endeavors to protect and without which individuals' ability to continue obtaining lawful health care services is impaired. Appx. 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). The Rule is consistent with Congress's express delegation of authority, and the Department has always been clear as to how covered entities should continue to make permissible disclosures in response to law enforcement requests. *See*, *e.g.*, Appx. 405–421 (89 Fed. Reg. at 33009–25 (Apr. 26, 2024)).

Nor does the 2024 Rule, as Plaintiff argues, implicate the major questions doctrine. The major questions doctrine applies only when an agency "claims the power to resolve a matter of great political significance"... 'seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities"... [or] 'seeks to intrude

Notification Rule was added to the privacy rules in response to passage of the HITECH Act. 74 Fed. Reg. at 42740 (Aug. 24, 2009). In 2013, the Omnibus Rule modified the Privacy Rule to strengthen protection of genetic information in response to the Genetic Information Non-Discrimination Act. 78 Fed. Reg. at 5566 (Jan. 25, 2013). In 2014, the Privacy Rule was modified in response to the Clinical Laboratory Improvement Amendments (CLIA) regulations. 79 Fed. Reg. at 7290 (Feb. 6, 2014). And a 2016 Privacy Rule change allowed covered entities to disclose PHI to the National Instant Criminal Background Check System. 81 Fed. Reg. at 382 (Jan. 6, 2016).

into an area that is the particular domain of state law." *Mayfield v. U.S. Dep't of Lab.*, 117 F.4th 611, 616 (5th Cir. 2024) (quoting *West Virginia v. EPA*, 597 U.S. 697, 743–44 (2022) (Gorsuch, J., concurring)). That is not the case here, as the disclosure of health care records is not a matter of great political significance, the changes of the 2024 Privacy Rule do not implicate a significant portion of the economy, and the 2024 Privacy Rule is not an intrusion into state law but instead is grounded in authority the agency has had for decades, since HIPAA's 1996 mandate for the Secretary to promulgate rules that address the "uses and disclosures" of personal health information. Appx. 561 (42 U.S.C. § 1320d-2 note).

When evaluating whether an agency violates the major questions doctrine, courts must examine whether the agency derives its authority from "the vague language of an ancillary provision of the Act," *West Virginia*, 597 U.S. at 724 (citation omitted), or "whether the agency has previously claimed the authority at issue." *Mayfield*, 117 F.4th at 617; *see also West Virginia*, 597 U.S. at 725. An agency action is more likely to violate the major questions doctrine when it effectuates "a fundamental revision of the statute, changing it from [one sort of scheme] of . . . regulation' into an entirely different kind," *West Virginia*, 597 U.S. at 728 (citation omitted), or when the "agency has no comparative expertise' in making certain policy judgments." *Id.* at 729 (citation omitted); *see also King v. Burwell*, 576 U.S. 473, 474 (2015) ("It is especially unlikely that Congress would have delegated this decision to the IRS, which has no expertise in crafting health insurance policy of this sort."). None of these circumstances are present here.

First, HHS did not "exercise powers of vast . . . political significance," Alabama Ass'n of Realtors v. U.S. Dep't of Health & Hum. Servs., 594 U.S. 758, 764 (2021) (internal quotations omitted), nor does the 2024 Rule seek to "resolve a matter of great political significance." Mayfield, 117 F.4th at 616. The 2024 Rule merely reinforces the privacy protections regarding the disclosure

of health care records for lawful care. *See*, *e.g.*, 45 C.F.R. § 164.502(a)(5)(iii)(B) (prohibiting disclosure when the "reproductive health care is lawful *under the law of the state* in which such health care is provided," or "protected, required, or authorized by Federal law") (emphasis added). This limited action is consistent with HHS's well-established authority under HIPAA because it only regulates how health care records are handled *after* care has been sought—not whether that care should be sought in the first instance. *See*, *e.g.*, *id.* § 160.103 (stating that the reproductive health care definition "shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care"); *id.* § 164.502 (regulating "uses and disclosures of protected health information").

Second, the economic impact of the 2024 Rule bears no similarity to the "billions of dollars in spending" that have triggered the doctrine in other instances. See, e.g., Mayfield, 117 F.4th at 616; see also Biden v. Nebraska, 600 U.S. 477, 502 (2023) (finding the major questions doctrine to be implicated when the government cancelled \$430 billion in student loans, resulting in costs to the taxpayer estimated to be "between \$469 billion and \$519 billion"); Alabama Ass'n of Realtors, 594 U.S. at 764 (finding the major questions doctrine applied to the COVID-19 eviction moratorium, the economic impact of which was estimated to be around "\$50 billion"). Rather, before enacting the Rule, HHS estimated that the total first-year costs attributable to it would amount to \$595 million. Appx. 445 (89 Fed. Reg. at 33049 (Apr. 26, 2024)). The Rule does not "substantially restructure" any market or have any impact on GDP at all. West Virginia, 597 U.S. at 715, 724 (noting that the Clean Power Plan was projected to "reduce GDP by at least a trillion 2009 dollars by 2040" in support of invoking the major questions doctrine).

Third, the 2024 Rule does not "intrude[] into an area that is the particular domain of state law," Alabama Ass'n of Realtors, 594 U.S. at 764, nor has HHS grounded its authority in "the

vague language of an 'ancillary provision[]' of the Act," or "effected a 'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind." West Virginia, 597 U.S. at 724, 728 (citations omitted). The 2024 Rule's disclosure prohibition is an exercise of the Department's core authority under HIPAA to promulgate rules concerning permissible "uses and disclosures" of PHI, Appx. 561 (42 U.S.C. § 1320d-2 note), and to adopt appropriate modifications to those rules. 42 U.S.C. § 1320d-3(b)(1). It has exercised that authority under the statute for decades. See Appx. 378 (89 Fed. Reg. at 32982–83 (Apr. 26, 2024)). Finally, not only is HHS the agency with "comparative expertise in making certain policy judgments," West Virginia, 597 U.S. at 729 (internal quotations omitted), but it is also the agency to which Congress explicitly delegated rulemaking authority in the plain language of HIPAA. Appx. 561 (42 U.S.C. § 1320d-2 note). HHS acted well within its Congressional mandate in promulgating the 2024 Rule.

III. The 2024 Rule Is Not Arbitrary and Capricious

The administrative record proves that HHS engaged in extensive, reasoned analysis before promulgating the 2024 Privacy Rule. In asserting that the 2024 Rule is arbitrary and capricious, Plaintiff fails to identify a single relevant factor or reliance interest that the Department did not consider. *See* Pl.'s Br. at 34-36; *Huawei Techs.*, 2 F.4th at 451 (rejecting APA claim where "agency weighed the evidence differently than [plaintiff] and reached contrary but reasonable policy conclusions").

In conducting arbitrary and capricious review under the APA, the Court is to presume the agency's final action is valid and is to consider only whether that action "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *see also Barr*, 114 F.4th at 447 ("Agency decisions are 'presumptively valid; the [petitioner] bears the burden of showing

otherwise.") (quoting *Tex. Tech Physicians Assocs. v. U.S. Dep't of Health & Hum. Servs.*, 917 F.3d 837, 844 (5th Cir. 2019) (brackets in original)). The Court's review is "neither sweeping nor intrusive." *Fort Bend Cnty. v. U.S. Army Corps of Eng'rs*, 59 F.4th 180, 194 (5th Cir. 2023). It may not "substitute its judgment for that of the agency." *Overton Park*, 401 U.S. at 416.

The Department's explanation for adopting the 2024 Rule readily meets this "narrow and highly deferential" standard. Huawei Techs., 2 F.4th at 456 (internal quotations omitted). After consulting with federal and state agencies and the National Committee on Vital Health and Statistics and considering more than 25,900 comments representing approximately 51,500 individuals and 350 organizations, the Department found that "th[e] changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system." Appx. 374 (89 Fed. Reg. at 32978 (Apr. 26, 2024)). It further determined that minimum protections and amendments to the Privacy Rule were needed to "provide[] peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." Id.; see also Appx. 372, 387 (89 Fed. Reg. at 32976, 32991 (Apr. 26, 2024)); FCC v. Fox TV Stations, Inc., 556 U.S. 502, 515 (2009) (An agency does not act in an arbitrary and capricious manner by improving a regulatory scheme where "the new policy is permissible under the statute, [] there are good reasons for it, and [] the agency believes it to be better.") (emphasis in original).

The Department also reasonably explained each of the Rule's requirements, including how covered entities determine the legality of reproductive health care when applying the 2024 Rule's disclosure prohibition. *See*, *e.g.*, Appx. 405–428 (89 Fed. Reg. at 33009–32 (Apr. 26, 2024)). "[W]here a request for PHI is made to the regulated entity that provided the relevant reproductive

health care," that entity should review "all available relevant evidence bearing on whether reproductive health care was lawful under the circumstances in which it was provided." Appx. 411 (89 Fed. Reg. at 33015 (Apr. 26, 2024)). Health care providers presumably must already assess the legality of any services that they provide to their patients, and the Rule's provisions are no different. Conversely, the Rule recognizes that when a covered entity did not provide the reproductive health care at issue, "it may not have access to all of the relevant information" to make a legal determination and is "not expected to conduct research or perform an analysis of an individual's PHI." Appx. 411 (89 Fed. Reg. at 33015 (Apr. 26, 2024)) (emphasis added). The covered entity is also "not required to make a determination about the lawfulness of such health care." Appx. 408 (89 Fed. Reg. at 33012 (Apr. 26, 2024)) (emphasis added). Instead, the entity can "presume[]" that the care is "lawful" unless it has "either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis that the reproductive health care was not lawful." Appx. 410 (89 Fed. Reg. at 33014 (Apr. 26, 2024)); see 45 C.F.R. § 164.502(a)(5)(iii)(C).

The Department also provided a detailed account of how covered entities can comply with the attestation requirement. *See, e.g.*, Appx. 425–28 (89 Fed. Reg. at 33029–32 (Apr. 26, 2024)). It explained that the attestation serves to alleviate "difficult[y] for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose" by requiring the relevant state or federal agency to provide certain forms of information to the covered entity when they seek information potentially related to reproductive health care, Appx. 425–26 (89 Fed. Reg. at 33029–30 (Apr. 26, 2024)), and described when covered entities are entitled to rely solely on the attestation and when they should consider additional factors, Appx. 427–28 (89 Fed. Reg. at 33031–32 (Apr. 26, 2024)). The Department

also provided a model attestation form and other resources to assist covered entities in applying the Rule.

Plaintiff's assertion that the Department failed to consider the reliance interests of parties subject to the 2024 Rule—namely, because it purportedly did not consider how the 2024 Rule would impact Plaintiff's ability to conduct audits—falls flat. Pl.'s Br. at 34–35. The Department consulted agencies at both the state and federal level, in addition to considering over 25,900 comments from about 350 interested organizations. Indeed, Plaintiff concedes that the Department considered how the Rule might impact health data collection and auditing. *See* Pl.'s Br. at 35 ("HHS considered information highlighting the importance of vital statistics, including mortality surveillance"). It therefore does not follow that it neglected to consider how the 2024 Rule would impact audits for entities related to federal program participation. Plaintiff may disagree with the policy conclusions reached by the Department based on its consideration of the issue, but mere policy disagreements do not give rise to an arbitrary and capricious challenge.

To the extent Plaintiff alleges delays to the usual timing of such audits are a result of the 2024 Rule and attestation requirements, a period of acclimation to a new rule does not render the rule arbitrary and capricious. HHS even detailed how covered entities can comply with the attestation requirement, proving that it thoughtfully considered and attempted to alleviate any confusion surrounding the new step. *See, e.g.*, Appx. 425–28 (89 Fed. Reg. at 33029–32 (Apr. 26, 2024)). Plaintiff merely points to scenarios where requests for information have been "delayed" because covered entities invoked the "extra step" of the attestation requirement or members of the Texas Department of State Health Services have sought legal counsel. Pl.'s Br. at 24–25. These routine compliance activities do not and cannot rise to the level of disregarding serious reliance interests such that HHS' action in promulgating the 2024 Rule was arbitrary and capricious.

Plaintiff's remaining arguments that the 2024 Rule is arbitrary and capricious likewise fail. Plaintiff argues that "[i]t is not reasonable to require covered entities to independently make complex legal judgments outside their usual purview before they may comply with Texas's requests for necessary information." Pl.'s Br. at 36. But it ignores the scores of descriptions and examples of how covered entities can comply with the Rule's requirements. See, e.g., Appx. 405– 28 (89 Fed. Reg. at 33009-32 (Apr. 26, 2024)). The fact that the 2024 Rule requires covered entities to determine whether governmental requests for information are valid is "consistent with the current and longstanding practice under the Privacy Rule" where covered entities are responsible for determining the applicability of the Privacy Rule's permitted disclosures. Appx. 409 (89 Fed. Reg. at 33013 (Apr. 26, 2024)). Further, the Privacy Rule requires covered entities to make assessments involving "applicable law" to determine the authority of a "personal representative," 45 C.F.R. § 164.502(g), provide information about a deceased patient, id. § 164.512(g), and disclose information relevant to a serious health threat, id. § 164.512(j). Plaintiff has put forward no explanation for why covered entities can comply with those requirements but cannot ascertain the validity of the government's request for PHI. See Pl.'s. Br. at 36.

Nor does the Rule require covered entities to "ignore what they may know" about state law. Pl.'s Br. at 36. The Department was clear that "if a person obtains reproductive health care that was unlawful" then the Rule's "prohibition does not apply" and PHI may be disclosed consistent with the Rule. Appx. 408 (89 Fed. Reg. at 33012 (Apr. 26, 2024)); see 45 C.F.R. § 164.502(a)(5)(iii)(B). The Rule's prohibitions would therefore be inapplicable if a covered entity had actual knowledge or a substantial factual basis to conclude that the care provided by someone else violates State law. See Appx. 408 (89 Fed. Reg. at 33012 (Apr. 26, 2024)); 45 C.F.R. § 164.502(a)(5)(iii). Nor is it unreasonable, let alone a "clear error of judgment," Overton Park, 401

U.S. at 416, to require covered entities to determine whether the reproductive health care they provide is "protected, required, or authorized by Federal law," 45 C.F.R. § 164.502(a)(5)(iii)(B)(2), when they presumably must already determine the legality of the care that they provide under federal law in their usual course of professional practice or rely on the presumption of lawfulness if the care was provided by another entity, *id.* § 164.502(a)(5)(iii)(C).

In light of this record, Plaintiff cannot show that the Department engaged in action that was "arbitrary, capricious, [or] an abuse of discretion" when promulgating the 2024 Rule. 5 U.S.C. § 706(2)(A).

IV. Any Remedies Should Be Limited to Plaintiff and Comply With HIPAA's Severability Provision

For the reasons stated, this Court should deny Plaintiff's motion in its entirety and enter judgment for the Defendants. But if the Court enters judgment for Plaintiff, the Court should limit any relief to the Plaintiff itself. Any further relief would be overbroad and defy the Department's clear intention of severability.

Any remedy the Court orders should account for the unambiguous severability provision contained in HIPAA's implementing regulations, which directs that "[i]f any provision . . . is held to be invalid or unenforceable . . . as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law." 45 C.F.R. § 164.535. Whether a regulation is severable depends upon (1) "the intent of the agency" and (2) "whether the remainder of the regulation could function sensibly without the stricken provision." *Texas v. United States*, 126 F.4th 392, 419 (5th Cir. 2025). Courts "adhere to the text of a severability clause in the absence of extraordinary circumstances." *Id.* (citation omitted).

The 2024 Rule satisfies both prongs. The Rule unequivocally provides that the Department "intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable,

the remaining provisions of the rule will remain in effect because they would still function sensibly." Appx. 444 (89 Fed. Reg. at 33048 (Apr. 26, 2024)). And the severability provision explicitly contemplates injunctions as to "persons" and "plaintiff[s]," indicating that any injunctive relief should apply only to the plaintiff before the Court. 45 C.F.R. § 164.535.

The 2024 Rule could also still function without the provisions challenged by Plaintiff. As explained in the 2024 Rule and in Defendants' brief, the Court could simply enjoin the Department from enforcing the Rule with respect to conditions requiring disclosures for law enforcement purposes or the Court can sever definitions of certain terms from the remainder of the Rule's provisions if it finds they are improper. *See* Appx. 444 (89 Fed. Reg. at 33048 (Apr. 26, 2024)); Defs.' Mem. at 30–31. Thus, any relief ordered should not transgress the Department's clear intention of severability, which would imperil protections that are vital to safeguard Americans' sensitive medical information.

More limited relief also accords with fundamental constitutional principles. Under Article III, "a plaintiff's remedy must be 'limited to the inadequacy that produced [their] injury in fact." Gill v. Whitford, 585 U.S. 48, 66 (2018) (quoting Lewis v. Casey, 518 U.S. 343, 357 (1996)); see United States v. Nat'l Treasury Emps. Union, 513 U.S. 454, 477–78 (1995) ("[W]e neither want nor need to provide relief to nonparties when a narrower remedy will fully protect the litigants."); Texas v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 700 F. Supp. 3d 556, 572 (S.D. Tex. 2023). An injunction with respect to the State of Texas alone would fully remedy Plaintiff's asserted injuries by barring Defendants from enforcing the 2024 Rule against Plaintiff. See Bureau of Alcohol, Tobacco, Firearms & Explosives, 700 F. Supp. 3d at 572 ("Equitable remedies, like remedies in general, are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit." (citation omitted)); California v. Texas, 593 U.S. 659, 672 (2021) (valid

Article III remedies generally "operate with respect to specific parties" rather than in the abstract (citation omitted)); Califano v. Yamasaki, 442 U.S. 682, 702 (1979) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs."); Texas v. United States, 126 F.4th 392, 420 (5th Cir. 2025) ("Remedies must be 'tailored to redress' a plaintiff's injury . . . and equitable remedies . . . should not provide more relief than 'necessary to give the prevailing party the relief to which [it] is entitled'" (citations omitted)). Plaintiff incorrectly characterizes Defendants as seeking vacatur "limited to the State of Texas." Pl.'s. Br. at 37. But Defendants do not argue for state-specific vacatur and instead note, consistent with Proposed Intervenors' briefing and Supreme Court precedent, that plaintiff-specific injunctions are properly-scoped equitable relief. Gill, 585 U.S. at 73 (2018) ("remedy must be tailored to redress the plaintiff's particular injury"); Yamasaki, 442 U.S. at 702 (1979).

Whether vacatur is appropriate turns on "the seriousness of the deficiencies of the action" and "the disruptive consequences of vacatur." *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021). Here, universal vacatur would have deeply disruptive consequences and cause nationwide harms to all of the other regulated parties, as well as the public's interest in the privacy of sensitive medical information. As set forth in Defendants' Brief, disclosures of such information would "irreparably harm relationships and reputations"; "result in job loss or other negative consequences in the workplace"; "deter[] [individuals] from seeking needed health care if they do not trust that their sensitive information will be kept private"; and withhold probative information from providers "necessary . . . for an appropriate treatment plan." Defs.' Mem. at 29–30 (quoting 89 Fed. Reg. at 32984, 32991, 33057). The Court should deny Plaintiff's blanket request. *See Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (en banc) (plurality opinion) *aff'd*, 602 U.S. 406 (2024) (remanding and stating that the district court could consider on remand "a more limited

remedy" than universal vacatur, and should "determine what remedy . . . is appropriate to effectuate" the judgment); *Central & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding without vacatur).

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiff's motion for summary judgment.

* * *

Date: June 30, 2025 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

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